DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0325]

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Medical Devices; Draft Guidance; Medical Devices Made With Polyvinylchloride Using the Plasticizer di-(2–Ethylhexyl)phthalate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA." Through this draft guidance, FDA is proposing to offer suggestions to manufacturers who fabricate their PVC devices using the plasticizer DEHP. The guidance recommends ways that manufacturers may reduce or eliminate potential risks that may be associated with DEHP. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville,

NAD 1

MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:/ /www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Robert Gatling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

DEHP is recognized as an important chemical ingredient that affords PVC many of the physical properties that make the material optimally suited for use in many of today's medical devices. DEHP is a chemical whose long-term effects on the human body are unknown. In this draft guidance, FDA is suggesting that manufacturers label certain devices with their DEHP content and consider eliminating the use of DEHP in certain devices that can result in high aggregate exposures in sensitive patient populations.

FDA recognizes that many devices with PVC containing DEHP are not used in ways that result in significant human exposure to the chemical. Therefore, this draft guidance focuses on the small subset of medical devices where PVC containing DEHP may come in contact with the tissue of a sensitive patient population in a manner and for a period of time that may raise concerns about the aggregate exposure to DEHP.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on medical devices made with PVC using the plasticizer DEHP. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive the "Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2–Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1407) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be

accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

IV. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. You must submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the

heading of this document. The draft guidance document and any received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/28/02
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Linda S. Kahan

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